

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

**Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934**

February 2, 2012

Date of Report (Date of earliest event reported)

Discovery Laboratories, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation)

000-26422

(Commission File Number)

94-3171943

(IRS Employer Identification Number)

**2600 Kelly Road, Suite 100
Warrington, Pennsylvania 18976**
(Address of principal executive offices)

(215) 488-9300

(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 8.01. Other Events.

On February 2, 2012, Discovery Laboratories, Inc. (the “Company”) issued a press release announcing that it had completed the registration of its initial Afectair® product with the U.S. Food and Drug Administration (FDA) and that it anticipates initiating the commercial introduction of the initial Afectair product in the United States and the European Union in late 2012. Afectair is the trademark for the Company’s proprietary ventilator circuit / patient interface connectors that simplify the delivery of inhaled therapies to critical care patients requiring ventilatory support by introducing the inhaled therapy directly at the patient interface and minimizing the number of connections in the ventilator circuit. The Company believes that, after an up-take period following the introduction of Afectair in the United States and the European Union, peak revenues could potentially be between \$50 million and \$75 million in the fourth full year of sales, which could occur as early as 2016. A copy of the release is attached hereto as Exhibit 99.1 and the text of such release is incorporated by reference herein.

The Company’s lead drug product, Surfaxin® for the prevention of respiratory distress syndrome in premature infants, is under review by the FDA, which has established March 6, 2012 (PDUFA Date) as its target action date under the Prescription Drug User Fee Act (PDUFA) to complete its review of the Surfaxin New Drug Application (NDA). The review activities are continuing and the Company believes that it is on track to hear from the FDA on or around the PDUFA Date.

Since the Company filed its Quarterly Report on Form 10-Q for the third quarter of 2011 on November 11, 2011, the Company has not utilized its Committed Equity Financing Facility (CEFF) with Kingsbridge Capital Limited (Kingsbridge) or the “at-the-market” program (ATM Program) that it put in place with Lazard Capital Markets, LLC, in December 2011. The Company also reports that it expects its net cash outflows in the fourth quarter of 2011 to be consistent with the outlook provided in November 2011, subject to normal year-end audit and related activities currently in process.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

[99.1](#) Press release dated February 2, 2012

Cautionary Note Regarding Forward-looking Statements:

To the extent that statements in this Current Report on Form 8-K are not strictly historical, including statements as to business strategy, outlook, objectives, future milestones, plans, intentions, goals, future financial conditions, future collaboration agreements, the success of the Company’s product development, the Company’s outlook regarding the results of the fourth quarter of 2011 or otherwise as to future events, such statements are forward-looking, and are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. The forward-looking statements contained in this Current Report are subject to certain risks and uncertainties that could cause actual results to differ materially from the statements made. Such risks and others are further described in the Company’s filings with the Securities and Exchange Commission including the most recent reports on Forms 10-K, 10-Q and 8-K, and any amendments thereto.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Discovery Laboratories, Inc.

By: /s/ W. Thomas Amick

Name W. Thomas Amick

Title Chairman of the Board and Chief Executive Officer

Date: February 2, 2012



DISCOVERY LABS CLEARED TO MARKET AFECTAIR IN U.S.

*New, Proprietary Technology Simplifies Delivery of Aerosolized Medications to Patients
Requiring Ventilatory Support – Conference Call to be held today at 10:00 a.m. (ET)*

Warrington, PA — February 02, 2012— Discovery Laboratories, Inc. (NASDAQ: DSCO), a specialty biotechnology company dedicated to advancing a new standard in respiratory critical care, today announced AFECTAIR® is now registered with the Food and Drug Administration (FDA) and is cleared to be marketed in the United States. AFECTAIR® is a proprietary patient interface technology that simplifies delivery of aerosolized medications to patients requiring ventilator support.

“We are pleased to have AFECTAIR registered with the FDA and we are eager to move this proprietary technology to commercialization in the latter part of 2012,” said W. Thomas Amick, Chairman of the Board and Chief Executive Officer of Discovery Labs. “Our ability to bring AFECTAIR to market is a testament to our commitment to advancing a new standard in respiratory critical care.”

AFECTAIR originates from the AEROSURF® development program and is a proprietary disposable ventilator circuit/patient interface connector that simplifies the delivery of aerosolized medications to critical-care patients requiring ventilatory support from either intermittent mechanical ventilation or continuous positive airway pressure. To date, *in vitro* studies suggest that the AFECTAIR technology may be an effective new solution for delivering aerosolized medicine to patients receiving ventilator support while providing healthcare professionals with a simplified alternative to current practices. According to national health statistics and market assessment data, it is estimated that each year more than 1.3 million patients in the United States and European Union receive aerosolized medications while requiring ventilator support. It is estimated that AFECTAIR represents a potential revenue opportunity of approximately \$50-75 million for Discovery Labs.

“In preparation for this milestone, we identified a number of operational and commercial options intended to support the commercial introduction of AFECTAIR,” said Thomas F. Miller, Senior Vice President and Chief Operating Officer of Discovery Labs, “We are now focused on implementing a commercial plan that includes the establishment of key strategic manufacturing and distribution relationships.”

Discovery Labs is also pursuing a European Conformity (CE) marking for commercialization of the initial AFECTAIR products in the European Union (EU) and believes that it may be in a position to initiate the commercial introduction of the initial AFECTAIR products in EU in late 2012.

CONFERENCE CALL DETAILS

Discovery Labs will hold a conference call today at 10:00 AM ET to further discuss the foregoing. The call in number is (877) 215-0093. The international call in number is (706) 679-3237. This audio webcast will be available through a live broadcast on the Internet at http://us.meeting-stream.com/discoverylaboratories_020212 and www.discoverylabs.com. The replay number to hear the conference call is (855) 859-2056 or (404) 537-3406. The passcode is 49011930.

ABOUT AFECTAIR

AFECTAIR is a series of proprietary ventilator circuit/patient interface connectors and related componentry. AFECTAIR simplifies the delivery of inhaled therapies to critical care patients requiring ventilatory support. According to national health statistics and market assessment data, it is estimated that each year more than 1.3 million patients in the United States and European Union receive aerosolized medications while requiring ventilator support. Discovery Labs is implementing a business plan that potentially will allow for the commercial introduction of AFECTAIR in the United States and the European Union in 2012.

ABOUT AEROSURF

AEROSURF (lucinactant for inhalation), Discovery Labs' initial aerosolized KL₄ surfactant product, is under development for the prevention of RDS in premature infants. Through effective delivery of aerosolized KL₄ surfactant using Discovery Labs' proprietary capillary aerosol generator technology and related ventilator circuit / patient interface connectors, AEROSURF may significantly expand the surfactant-eligible treatment population by providing neonatologists with a means of administering surfactant without the risks currently associated with surfactant administration, which requires invasive endotracheal intubation and mechanical ventilation.

ABOUT DISCOVERY LABS

Discovery Laboratories, Inc. is a specialty biotechnology company with one focus – to create life-saving products for patients with respiratory disease and improve the standard of care for pulmonary medicine. Discovery Labs' novel proprietary KL₄ surfactant technology produces a synthetic, peptide-containing surfactant that is structurally similar to pulmonary surfactant and is being developed in liquid, lyophilized and aerosol dosage forms. Discovery Labs is also developing its proprietary drug delivery technologies – the capillary aerosol generator and the novel ventilator circuit / patient interface connectors – to enable efficient, targeted upper respiratory or alveolar delivery of aerosolized KL₄ surfactant. Discovery Labs believes that its proprietary technologies makes it possible, for the first time, to develop a significant pipeline of surfactant products to address a variety of respiratory diseases for which there frequently are few or no approved therapies. For more information, please visit our website at www.Discoverylabs.com.

Forward-Looking Statements

To the extent that statements in this press release are not strictly historical, all such statements are forward-looking, and are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from the statements made. Examples of such risks and uncertainties, including those related to AFECTAIR, are described in Discovery Labs' filings with the Securities and Exchange Commission including the most recent reports on Forms 10-K, 10-Q and 8-K, and any amendments thereto. Any forward-looking statement in this release speaks only as of the date on which it is made. The Company assumes no obligation to update or revise any forward-looking statements.

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